

Remarks

Claims 1-46 were pending in this application, and subject to a Restriction Requirement. Claims 39-46 have been canceled herein, without prejudice to renewal. Applicants expressly reserve the right to pursue protection of any or all of the canceled subject matter in one or more divisional or continuing applications. Claim 2 is amended herein to correct form, and new claim 47 is added. Support for new claim 47 can be found throughout the specification, for example on page 17, line 21.

After entry of this amendment, **claims 1-38 and 47 are pending in the application.**

Substantive examination of the pending claims is requested.

Restriction Requirement

In response to the restriction requirement, Applicants provisionally elect, with traverse, the claims of Group I, directed to a method of preventing or treating an IgA mediated autoimmune disorder (claims 1-8, 18-23 and 36-38).

The Office action alleges that Groups I-IV do not relate to a special technical feature that defines the contribution over PCT Publication No. WO 98/53846 (hereinafter “the ‘846 publication”). Applicants respectfully disagree with this assertion. The ‘846 publication discloses the use of uteroglobin to treat inflammatory conditions and fibrotic conditions. Bronchial asthma is discussed in the ‘846 publication (see, for example, page 3). However, bronchial asthma is an IgE mediated disorder.

It is solely the present disclosure that teaches that uteroglobin can be used to treat disease associated with increased IgA, such as IgA nephropathy, which accounts for only a subset of glomerulonephritis. In addition, it is solely the present specification that discloses that uteroglobin can be used to treat pulmonary disorders associated with increased IgA, such as Goodpasture’s disease. Thus, the general teachings of the ‘846 publication do not suggest, nor render obvious, the use of uteroglobin to treat a subset of individuals affected with IgA mediated autoimmune disease, such as those individuals with IgA mediated nephropathy or pulmonary disorders. It is only the teachings of the present specification that provides this insight.

Moreover, it is only the present specification that discloses a screening test to identify those subjects or patients with nephropathy (or pulmonary disorders) who would be most likely to benefit from treatment with uteroglobin. Since subjects affected with IgA mediated autoimmune disorders

rapidly develop life threatening conditions, it is essential to know that a certain subset of those patients (who have IgA associated disorders) should be selected for uteroglobin treatment.

Thus, Groups I-IV relate to a special technical feature, namely the treatment and diagnosis of a IgA mediated disorder, that is novel and non-obvious over the '846 publication. Reconsideration and withdrawal of the restriction requirement is respectfully requested.

The Office action further requires the election of a single species of IgA-mediated disorders if Group I is elected, as recited in claim 2. In response, Applicants elect IgA mediated nephropathy, with traverse.

Applicants thank the Examiner for noting that claims 1-2 and 4-9 are generic. Applicants believe that claims 18-23 are also generic. Applicants thank the Examiner for confirming that upon the allowance of a generic claim, that the Applicants are entitled to consideration of claims to additional species that are written in dependent form or otherwise include all the limitation of an allowed generic claims as provided by 37 C.F.R. § 1.141.

Conclusion

It is respectfully submitted that the amended claims submitted herewith should all be recombined and considered in the current case, and as such they are in a condition for substantive examination. If an additional restriction requirement is asserted, or if the present restriction requirement is maintained, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

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